

Curriculum Vitae

Steven A. Berkowitz, Ph.D.

Sudbury, Massachusetts, USA

Employment History

2014–present: Retired; provide technical consulting services.

1993–2014: Biogen Inc., Cambridge, MA — Senior Principal Scientist.

1991–1993: Lederle Laboratories, Pearl River, NY — Senior Biochemist.

1984–1991: J.T. Baker Inc., Phillipsburg, NJ — Senior Scientist.

1980–1984: Celanese Research Company, Summit, NJ — Research Chemist.

1978–1980: National Institutes of Health, Bethesda, MD — Staff Fellow in the laboratory of Dr. Jan Wolff.

1976–1978: Yale University, New Haven, CT — Research Associate in the laboratory of Dr. Julian Sturtevant.

1975–1976: Yale University, New Haven, CT — Postdoctoral Fellow in the laboratory of Dr. Robley Williams Jr.

Education

1978–1980: George Washington University, Washington, D.C. — Graduate coursework in Electrical Engineering & Computer Science.

1968–1975: New York University, New York, NY — Ph.D. in Biochemistry — Dr. Loren Day, Supervisor.

1964–1968: Fairleigh Dickinson University, Teaneck, NJ — B.S. in Biology.

Professional Memberships

- Biophysical Society
- American Chemical Society
- Protein Chemists Society
- American Association for the Advancement of Science (AAAS)

Publications

Kokona B., Vogt A., Whitaker N., O'Neill A., Ausman K.D., Wen J., De Leon A.L., Malecka K.A., Laue T.A., Berkowitz S.A., Kar S.R., "Particle size distribution resolution limit of AAV high-speed sedimentation velocity protocol relative to low-speed sedimentation velocity protocol, mass photometry, and charge-detection mass spectrometry", *J. Pharm. Sci.* 114(8):103878 (2025).

Berkowitz S.A., "History and progress in viral vector particle size distribution analysis", *Cell & Gene Therapy Insight.* 10(11), 1573-1581 (2024), DOI:10.18609/cgti.2024.180

Larson N.R., Bou-Assaf G.M., Laue T.M., Berkowitz S.A., "Using absorbance detection for hs-SV-AUC characterization of adeno-associated virus", *Anal. Biochem.* 694:115617 (2024).

Berkowitz S.A., Larson N., Bou-Assaf G., Laue T., "Rapid high-resolution size distribution protocol for adeno-associated virus using high speed SV-AUC", *Anal. Biochem.* 689:115482 (2024).

Berkowitz S.A., Laue T., "Boundary convection during sedimentation velocity in the Optima analytical ultracentrifuge", *Anal. Biochem.* 631:114306 (2021).

Houde D.J., Bou-Assaf G.M., Berkowitz S.A., "Deciphering the Biophysical Effects of Oxidizing Sulfur-Containing Amino Acids in Interferon-beta-1a using MS and HDX-MS", *J. Am. Soc. Mass Spectrom.* 28:840-849 (2017).

Iacob R.E., Bou-Assaf G.M., Makowski L., Engen J.R., Berkowitz S.A., Houde D., "Investigating monoclonal antibody aggregation using a combination of H/DX-MS and other biophysical measurements", *J. Pharm. Sci.* 102:4315-29 (2013).

Kulczyk A.W., Akabayov B., Lee S.J., Bostina M., Berkowitz S.A., Richardson C.C., "An interaction between DNA polymerase and helicase is essential for the high processivity of the bacteriophage T7 replisome", *J. Biol. Chem.* 287:39050-60 (2012).

Berkowitz S.A., Engen J.R., Mazzeo J.R., Jones G.B., "Analytical tools for characterizing biopharmaceuticals and the implications for biosimilars", *Nat. Rev. Drug Discov.* 11:527-40 (2012).

Houde D., Berkowitz S.A., "Conformational comparability of factor IX-Fc fusion protein, factor IX, and purified Fc fragment in the absence and presence of calcium", *J. Pharm. Sci.* 101:1688-700 (2012).

Li H., Bai S., Wei J.Y., Berkowitz S.A., Brader M.L., "Calcium binding to a factor ix Fc fusion protein and effects on higher-order structure", *J. Pharm. Sci.* 100:4597-606 (2011).

Houde D., Berkowitz S.A., Engen J.R., "The utility of hydrogen/deuterium exchange mass spectrometry in biopharmaceutical comparability studies", *J. Pharm. Sci.* 100:2071-86 (2011).

Pepinsky R.B., Silvian L., Berkowitz S.A., Farrington G., Lugovskoy A., Walus L., Eldredge J., Capili A., Mi S., Graff C., Garber E., "Improving the solubility of anti-LINGO-1 monoclonal antibody Li33 by isotype switching and targeted mutagenesis", *Protein Sci.* 19:954-66 (2010).

Houde D., Peng Y., Berkowitz S.A., Engen J.R., "Post-translational modifications differentially affect IgG1 conformation and receptor binding", *Mol. Cell Proteomics* 9:1716-28 (2010).

Kaltashov I.A., Bobst C.E., Abzalimov R.R., Berkowitz S.A., Houde D., "Conformation and dynamics of biopharmaceuticals: transition of mass spectrometry-based tools from academe to industry", *J. Am. Soc. Mass Spectrom.* 21:323-37 (2010).

Bobst C.E., Abzalimov R.R., Houde D., Kloczewiak M., Mhatre R., Berkowitz S.A., Kaltashov I.A., "Detection and characterization of altered conformations of protein pharmaceuticals using complementary mass spectrometry-based approaches", *Anal. Chem.* 80:7473-81 (2008).

Berkowitz S.A., "Determining the concentration and the absorptivity factor at 260 nm in sodium dodecyl sulfate of the adenovirus reference material using analytical ultracentrifugation", *Anal. Biochem.* 380:152-54 (2008).

Berkowitz S.A., Philo J.S., "Monitoring the homogeneity of adenovirus preparations (a gene therapy delivery system) using analytical ultracentrifugation", *Anal. Biochem.* 62:16-37 (2007).

Berkowitz S.A., "Role of analytical ultracentrifugation in assessing the aggregation of protein biopharmaceuticals", *AAPS J.* 8:E590-605 (2006).

Berkowitz S.A., Zhong H., Berardino M., Sosic Z., Siemiatkoski J., Krull I.S., Mhatre R., "Rapid quantitative capillary zone electrophoresis method for monitoring the micro-heterogeneity of an intact recombinant glycoprotein", *J. Chromatography A* 1079:254-65 (2005).

Berkowitz S.A., "Protein purification by multidimensional liquid chromatography", *Advances in Chromatogr.* 29:175-219 (1989).

Berkowitz S.A., "Silica-based chromatography products", *Bio/Technology* 5, 611 (1987).

Berkowitz, S.A., "Linear multidimensional liquid chromatography in protein separation", *J. Liquid Chromatogr.* 10, 2771 (1987).

Berkowitz, S.A., "Manipulation of the mobile phase to achieve multiple step protein (Calmodulin) purification using the same chromatographic material (a weak anion exchanger)", *J. Chromatogr.* 398, 288 (1987).

Berkowitz, S.A., Henry M.P., "Linear multidimensional liquid in the preparative scale purification of Calmodulin from brain extract", *Anal. Biochem.* 164, 254-60 (1987).

Berkowitz, S.A., "Use of high-performance hydrophobic interaction chromatography for the determination of salting-out conditions of proteins", *J. Chromatogr.* 389, 317-21 (1987).

Berkowitz S.A., "A strategic approach to the use of silica-based chromatography media (bonded phases) for protein purification", *American Laboratory*, May, 33 (1987).

Berkowitz, S.A., "Rejection of spike noise from size-exclusion chromatography-low angle laser light scattering experiments", *Anal. Chem.* 58, 2571 (1986).

Berkowitz, S.A., "Viscosity-molecular weight relationships for poly(ethylene terephthalate) in hexafluoroisopropanol-pentafluorophenol using SEC-LALLS", *J. Applied Polymer Sci.* 29, 4353 (1984).

Berkowitz S.A., "Specific refractive increment measurements on macromolecules using a Waters' 401 differential refractometer", *J. Liquid Chromatogr.* 6, 1359,(1983).

Goldhammer, A.R., Wolff J., Cook G.H., Berkowitz S.A., Klee C.B., Manclark C.R., Hewlett E.L., "Spurious protein activators of Bordetella pertussis adenylate cyclase", *Eur. J. Biochem.* 115, 605-9 (1981).

Berkowitz S.A., Wolff, J., "Intrinsic calcium sensitivity of tubulin polymerization", *J. Biol. Chem.* 256, 11216-23 (1981).

Berkowitz S.A., Wolff, J., Appendix: "A rapid composite chromatography procedure for purifying, concentrating and desalting tubulin", *J. Biol. Chem.* 256, 11223 (1981).

Wolff J., Cook G.H., Goldhammer A.R., Berkowitz S.A., "Calmodulin activates prokaryotic adenylate cyclase", *Proc. Natl. Acad. Sci. U.S.A.* 77, 3841-4 (1980).

Jackson M.B., Berkowitz S.A., "A kinetic model for microtubule assembly". *Proc. Natl. Acad. Sci. U.S.A.* 77, 7303-5 (1980).

Berkowitz S.A., Day L.A., "Turbidity measurements in an analytical ultracentrifuge. Determination of mass-per-length for the filamentous viruses fd, Xf and Pf3", *Biochemistry* 19, 2696-702 (1980).

Berkowitz S.B., Velicelebi G., Sutherland J.W.H., Sturtevant J.M., "Observation of an exothermic process associated with the in vitro polymerization of brain tubulin", *Proc. Natl. Acad. Sci. U.S.A.* 77, 4425 (1980),

Day L.A., Berkowitz S.A., Appendix: "The number of nucleotides and the density and refractive index increment of fd DNA", *J. Mol. Biol.* 116, 593 (1977).

Berkowitz S.A., Katagiri, J., Binder H.K., Williams R.C. Jr., Separation and characterization of microtubule proteins from calf brain", *Biochemistry* 16, 5610 (1977).

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Berkowitz S.A., Day L.A., "Mass, Length, composition and structure of the filamentous bacterial virus fd", *J. Mol. Biol.* 102, 531 (1976).

Detrich H.W. III, Berkowitz S.A. Kim H., William R.C. Jr., "Binding of glycerol by microtubule protein", *Biochem. and Biophys. Research Comm.* 68, 961 (1976).

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Berkowitz S.A., Day L.A., The molecular weight of fd DNA by equilibrium sedimentation and Rayleigh light scattering", *Biochemistry* 13, 4825 (1974).

Books and Book Chapters

Houde, D., Berkowitz, S.A. (Editors), Biophysical Characterization of Proteins in Developing Biopharmaceuticals, 2nd Edition, Elsevier (2019).

- Chapter 1– The Complexity of Protein Structure and the Challenges it Poses in Developing Biopharmaceuticals (Houde, D., Berkowitz, S.A.)
- Chapter 2 – Biophysical Characterization and Its Role in the Biopharmaceutical Industry (Houde, D., Berkowitz, S.A.)
- Chapter 3 – Biopharmaceutical Industry's Biophysical Toolbox (Houde, D., Berkowitz, S.A.)
- Chapter 4 – An Introduction and Hierarchical Organization of the Biophysical Tool in Section II (Houde, D., Berkowitz, S.A.)
- Chapter 7 – Size-Exclusion Chromatograph (SEC) in Biopharmaceutical Process Development (Houde, D. Berkowitz, S.A.)
- Chapter 8 – Scattering Techniques for the Characterization of Biopharmaceuticals (Makowski, L., Berkowitz, S.A., Houde, D.)

- Chapter 9 – Characterizing Biopharmaceuticals using Analytical Ultracentrifugation (Berkowitz, S.A., Philo, J.S.)
- Chapter 14 – Chromatography (other than size-exclusion chromatography) and electrophoresis (Berkowitz, S.A.)
- Chapter 15 – Challenges with the biophysical characterization of complex (multi-chain assembly, chemically modified, big and high concentration) biopharmaceuticals (Berkowitz, S.A.)
- Chapter 19 – Biophysical Characterization: An Integral Part of the "Totality of the Evidence" Concept (Houde, D., & Berkowitz, S.A.)

Endrenyi L., Declerck P., Chow S.-C. (Editors), Biosimilar Drug Products Development, CRC Press (2017).

- Chapter 2 – Analytical Characterization: Structural Assessment of Biosimilarity (Berkowitz S.A.)

Weis D.D. (Editor), Hydrogen Exchange Mass Spectrometry of Proteins. Wiley (2016).

- Chapter 13 – The Role of Hydrogen Exchange Mass Spectrometry in Assessing the Consistency and Comparability of the Higher-Order Structure of Protein Biopharmaceuticals (Houde, D., Berkowitz, S.A.)